



MEDICAL ADVISORY PANEL

STANDARDS AND GUIDELINES FOR RESEARCHERS

These guidelines have been produced to assist researchers who are submitting applications for research funding. All applications will be reviewed for ethical suitability, by the St John Human Research Ethics Committee.

PURPOSE

The purpose of these standards is to provide a structure for the conduct of clinical research and research-associated activities involving St John members, access to St John records and activities within St John. This policy will apply to all research performed by researchers requesting or utilising research data from within St John or associated with St John activities. For the purposes of this policy, research encompasses the investigation and review of clinical procedures and strategies on human subjects. It may be extended, at the discretion of the Medical Advisory Panel, to include appropriate laboratory research. This policy also covers any research funded through the annual St John research funds.

ETHICS RESOURCES

National Health and Medical Research Council (NHMRC):

- [National Statement on Ethical Conduct in Human Research \(2007\) - updated 2018.](#)
- [The Australian Code for the Responsible Conduct of Research](#)

STANDARDS

1. All research projects must be submitted to and approved by the St John Human Research Ethics Committee (EC00360), which is registered and authorised under NHMRC legislation.
2. The research must conform with the NHMRC National Statement on Ethical Conduct in Human Research, as given above.
3. Before research is undertaken, the free and informed consent of subjects must be obtained and subjects must be free to withdraw from the research at any stage.
4. Priority will be given to St John researchers in allocation of St John research funds.
5. All research work, materials and publications will remain the property of St John Ambulance Australia and the individual researchers.

ACCOUNTABILITY

Chair, St John Medical Advisory Panel

PREPARATION OF SUBMISSIONS

Submissions for proposed research to be undertaken should be prepared and submitted as detailed below. Researchers should use the [St John Research Application Form](#) in submitting applications for approval by the St John Human Research Ethics Committee. (St John's HREC is not currently included in the [HREA](#) system.)

The submission must be written in plain English, capable of being understood by a wide range of people where technical jargon is minimised.

A submission should include the following:

Project overview

- short title of research project
- project summary
- why this research should be conducted
- anticipated start and end dates.

Human resources

- name, address and qualifications/experience (including in research) of the principal investigator
- names and addresses of any co-researchers or project team
- name and address of the project supervisor (if applicable).

Project details

- level of research (see below)
- research questions
- research background (including outline of relevant literature)
- benefits to St John Ambulance Australia
- risks to participants and researchers
- methodology to be used (attach a copy of instruments to be used e.g. questionnaires)
- project plan (including proposed timeframe).

Participants

- population description and numbers
- description of what is required of participants
- how participants are recruited (attach a copy of the recruitment letter)
- how consent will be obtained – see below (attach a copy of the consent form).

Confidentiality/privacy

- what information is collected and how it is used
- how information will be stored securely (eg a password-protected shared drive) so as to ensure that only the researchers involved have access to the data
- plan for disposal of information collected.

Results dissemination

- intention to publish and target publications (publication plan, including reports)
- any conferences where it is planned to present results.

Budget

- A budget or schedule of intended expenditure
- funding source.

Other

- attach letter of approval from another human research ethics committee (if necessary where the research proposal requires approval from multiple human research ethics committees).

Note: It is critical that any surveys, questionnaires, letters and consent form (as required by the research methodology) are included with the application. The most common reason for applications not being endorsed by the St John Human Research Ethics Committee is one or more of these documents not being provided. All such documents (and the submission itself) should be written in plain and simple English, avoiding jargon.

LEVELS OF RESEARCH

Within St John Ambulance Australia, levels of research may include the following:

Audits and results analysis

Clinical audits generally assess quality control and assist in monitoring quality improvement activities. For example, adequacy of patient records; compliance with hand washing technique; retention of CPR skills.

Interpretation of data

A review of data relating to a situation, specific event or event type. For example, the types of cases seen at a fun run and the associated resource requirements.

Case studies and commentaries

Although not considered as pure research, a case study followed by a review of the literature in the area is a valuable educational activity. Topic reviews add to the body of available knowledge and can enhance understanding, and influence both procedures and practices. Case studies are generally prepared for presentation or publication. For example, an unusual case of severe headache with an associated review of the modes of headache presentation.

Note: Literature reviews do not require approval from the St John Human Research Ethics Committee.

Equipment evaluations

St John is frequently asked to evaluate and/or endorse products. A structured review of a product within the first aid environment according to determined criteria is an important trial. For example, comparing a new cervical collar device against existing St John equipment.

Evaluation of clinical care strategies

The evaluation of a procedure or process on the impact of clinical outcome is a highly desirable area for clinical research in first aid and patient care. For example, effectiveness of a response strategy in the outcome of cardiac arrest. Can CPR be sustained by all qualified first aiders for a minimum of 5 minutes?

Clinical trials

A clinical trial is defined as a structured examination or evaluation of the effectiveness of a process, procedure, therapeutic agent or intervention in a clinical situation, illness or disease. In general, a hypothesis is established and evaluated. This usually refers to the comparison of one or more treatments in the management of a clinical problem. Randomisation is said to have occurred when a patient has been assigned to a particular treatment group.

Prospective randomised single-blinded clinical trials

A clinical trial where the reviewer of the results is unaware of the treatment strategy employed. This type of activity is highly appropriate for the first aid and patient care environment. For example, is sling device A more effective than sling device B in resting the upper limb in fractures of the forearm?

Prospective randomised double-blinded clinical trials

A clinical trial where neither the reviewer nor the provider is aware of the treatment strategy employed. These trials are difficult to perform in the first aid and patient care environment. They usually refer to trials of therapeutic agents such as medications.

CONSENT

All studies involving human subjects require some form of consent from the participant or the participant's legal guardian. The identity of the latter will be guided by the various state legislations.

Informed consent

Many studies will require informed consent to be obtained from participants. Informed consent guarantees a subject in a study all of the following:

- explanation of the study
- freedom to choose whether the participant wishes to participate
- freedom to withdraw at any time
- an understanding of the risks and benefits
- guaranteed anonymity if the study is to be published or presented.

Unconscious and critically ill patients

Consent is generally unobtainable from this patient cohort. Therefore, researchers will be required to demonstrate how any intervention is intended or expected to benefit patients. In doing so, a synopsis or review of available knowledge with any associated scientific evidence in support of a therapeutic manoeuvre or intervention must accompany submissions or proposals.

Consent forms

Research applications should include a copy of an information sheet and consent form to be given to participants. For guidance on developing an information sheet and consent form, [see 'Ethical issues and resources' on the NHMRC website](#).

All consent forms must include the wording:

Approved by the St John Ambulance Australia Human Research Ethics Committee. For further details, contact St John's Medical Advisory Panel Secretariat: publications@stjohn.org.au, (02) 6239 9209.

SUBMISSION ENDORSEMENT

Endorsement by the State/Territory CEOs is required for any research originating from State/Territory and whenever State/Territory data is to be used, or State/Territory subjects are to be interviewed.

Endorsement from the National CEO is required for any research originating from national level.

COMMITTEE CONSIDERATIONS

All research proposals will be reviewed by the St John Human Research Ethics Committee. The Committee may give ethical approval to a submission without seeking further information. In many cases, the Committee may seek further information related to the submission prior to giving ethical approval.

The St John Human Research Ethics Committee will allocate a project number to all submissions received. This project number should be referenced in all correspondence between the researcher and the St John Human Research Ethics Committee.

Where a researcher is seeking funding from St John, the research proposal is presented to the National Board for endorsement. It will only be presented to the Board for endorsement if it has been given ethical approval by the St John Human Research Ethics Committee.

PROGRESS REPORTS

If a research project takes multiple years, annual progress reports are to be provided to the St John Human Research Ethics Committee. If progress reports are not submitted on time, the Human Research Ethics Committee may withdraw its endorsement of the project.

The content of progress reports will generally depend upon the nature of the project or study. However, it is expected that core information will include:

- review of available results
- where appropriate, the number of subjects entered into the study or the number of research protocol events
- application to change a research protocol or study design

- audit of critical or iatrogenic incidents
- presentation of any other adverse incidents
- discussion of any identified unforeseen circumstances or difficulties.

A reporting system will be in existence to record adverse outcomes. An audit of such events will be periodically conducted. Results and analysis of such events will be included in progress reports to the Medical Advisory Panel.

DEADLINE EXTENSIONS

For various reasons, researchers may find that they are unable to complete the research project by the completion date agreed with the St John Human Research Ethics Committee. In such a situation, the researcher should apply for an extension to the research project. If a final report is not submitted by the agreed completion date, the Human Research Ethics Committee may withdraw its endorsement of the project.

PUBLISHING

While not mandatory, it is highly desirable that researchers publish the results of their research. Researchers are to provide St John Ambulance Australia with a copy of articles published as a result of research under St John auspices.

Any such publication should acknowledge any support provided by St John Ambulance Australia and the ethical approval by the St John Human Research Ethics Committee.

Authors (of manuscripts and publications)

The following criteria for authorship have been modified from, and are consistent with, the document entitled '[Instructions for Authors](#)' from the Medical Journal of Australia.

In general, authorship will be based on demonstration of a significant contribution to the following:

- a. concept and design of the project, study or analysis, and interpretation of data
- b. critically drafting or revising an article for important intellectual content
- c. final approval of the version to be published.

Conditions (a), (b) and (c) must be satisfied, and each author must be willing to assume public responsibility for any publication.

PRESENTATION OF INFORMATION AT MEETINGS AND CONFERENCES

Any author may present the research at meetings and conferences. The Australian Office of St John Ambulance Australia is to be advised when any paper is being presented on behalf of St John, or where St John data or information is the primary subject of a paper presented at a major national or international meeting. It is recommended that the author notify the relevant St John State/Territory Office, if the research is being presented in their market. Any such presentation should acknowledge any support provided by St John Ambulance Australia, and the ethical approval by the St John Human Research Ethics Committee.

COMPLETED PROJECTS

Researchers for all research projects, where approval has been given by the St John Human Research Ethics Committee, must provide a final report on the project to the St John National Office by the agreed completion date for the project. If a final report is not submitted on time, the Human Research Ethics Committee may withdraw its endorsement of the project.

The final report should be either:

- a published article (as per publishing above) OR
- a manuscript in a form similar to that required for publication.

Any unexpended funds should be returned to St John Ambulance Australia.

REFERENCES

Medical Journal of Australia (MJA) Instructions for authors. Available from: <https://www.mja.com.au/journal/mja-instructions-authors>

National Health and Medical Research Council.

- [National Statement on Ethical Conduct in Human Research \(2007\) - updated 2018.](#)
- [The Australian Code for the Responsible Conduct of Research](#)
- [A guide to the development, evaluation and implementation of clinical practice guidelines](#)

Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3142758/>